WO 2004/085637 PCT/GB2004/001383

- 28 -

## **Claims**

- 1. A Clostridium difficile lactate dehydrogenase comprising the amino acid sequence of SEQ ID NO: 2, or an amino acid sequence exhibiting at least 70, 80, 90, 95, 96, 97, 98, 99, or 99.5% identity with the amino acid sequence of SEQ ID NO: 2.
- 2. An isolated nucleic acid molecule encoding the *Clostridium difficile* lactate dehydrogenase as claimed in claim 1.
- 10 3. An isolated nucleic acid molecule according to claim 2, comprising the nucleotide sequence of SEQ ID NO: 1.
  - 4. A nucleic acid vector comprising the nucleic acid molecule of either one of claims claim 2 or 3.
  - 5. A host cell containing the vector of claim 4.

5

15

20

- A process for producing a polypeptide comprising the Clostridium difficile lactate dehydrogenase according to claim 1, the process comprising culturing the host cell of claim 5 under conditions sufficient for the production of said polypeptide, and recovering said polypeptide.
- 7. A vector according to claim 4, wherein said vector is selected from the group consisting of a plasmid, a virus, and a bacteriophage.
- 8. A vector according to claim 7, wherein said isolated nucleic acid molecule is inserted into said vector in proper orientation and correct reading frame such that a polypeptide comprising the *Clostridium difficile* lactate dehydrogenase may be expressed by a cell transformed with said vector.

WO 2004/085637 PCT/GB2004/001383

- 9. A vector according to claim 8, wherein said isolated nucleic acid molecule is operatively linked to a promoter sequence.
- 10. An antibody or an antigen-binding fragment thereof specific against a Clostridium difficile lactate dehydrogenase according to claim 1.
  - 11. An antibody or an antigen-binding fragment thereof according to claim 10 for use in a method of treatment or diagnosis of the human or animal body.
- 10 12. A method of manufacture of a medicament for the treatment of a *Clostridium difficile* infection, comprising the use of an antibody or an antigen-binding fragment thereof according to claim 10.
- 13. A medicament, comprising a therapeutically effective quantity of an antibiotic and an antibody or an antigen-binding fragment thereof specific against a *Clostridium difficile* lactate dehydrogenase according to claim 1.
  - 14. A medicament according to claim 13 for use in a method of treatment or diagnosis of the human or animal body.

- 15. A medicament according to claim 13, being for the treatment of a *Clostridium difficile* infection.
- 16. A method of manufacture of a medicament for the treatment of a Clostridium difficile infection, characterised in the use of a therapeutically effective quantity of an antibiotic and an antibody or an antigen-binding fragment thereof specific against a Clostridium difficile lactate dehydrogenase according to claim 1.

WO 2004/085637 PCT/GB2004/001383

- 30 -

17. A method of treatment of *Clostridium difficile* infection, comprising the step of administering to a patient in need of same a therapeutically effective quantity of an antibiotic and an antibody or an antigen-binding fragment thereof specific against a *Clostridium difficile* lactate dehydrogenase according to claim 1.

5

20

- 18. A diagnostic test method for detecting the presence in a sample of a Clostridium difficile lactate dehydrogenase according to claim 1, comprising the steps of:
- i) contacting said sample with an antibody or an antigen-binding fragment thereof specific against said Clostridium difficile lactate dehydrogenase;
  - ii) detecting any antibody-antigen binding reaction; and
- iii) correlating the results of detection step (ii) with the presence of said Clostridium difficile lactate dehydrogenase in said sample.
  - 19. A diagnostic test method for detecting the presence in a sample of antibody specific against a *Clostridium difficile* lactate dehydrogenase according to claim 1 comprising the steps of:
    - i) contacting said sample with said *Clostridium difficile* lactate dehydrogenase;
    - ii) detecting any antibody-antigen binding reaction; and
    - iii) correlating the results of detection step (ii) with the presence of antibody specific against said *Clostridium difficile* lactate dehydrogenase in said sample.

10

- 20. A diagnostic test method according to either one of claims 18 or 19, the sample being a sample from a patient.
- A diagnostic test kit for performing a diagnostic test method according to any one of claims 18-20.
  - A pharmaceutical pack for the treatment of a *Clostridium difficile* infection, comprising a therapeutically effective quantity of an antibiotic and an antibody or an antigen-binding fragment thereof specific against a *Clostridium difficile* lactate dehydrogenase according to claim 1.
  - 23. A medicament, method of manufacture, method of treatment, diagnostic test method, diagnostic test kit, or pharmaceutical pack according to any one of claims 12-22, said antibiotic being vancomycin, ramoplanin, teicoplanin, or metronidazole.
  - 24. A medicament, method of manufacture, method of treatment, diagnostic test method, diagnostic test kit, or pharmaceutical pack according to any one of claims 12-22, said infection being due to *Clostridium difficile*.
- 25. A medicament, method of manufacture, method of treatment, diagnostic test method, diagnostic test kit, or pharmaceutical pack according to any one of claims 12-22, said bacterium being resistant to treatment by said antibiotic alone.